

# ***Update on Veronate***

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APPENDIX 2



# Veronate®

- Plasma-derived, donor-selected polyclonal IVIG
- High levels of IgG directed against staphylococcal proteins (MSCRAMM®)
  - *S. aureus* - ClfA
  - *S. epidermidis* - SdrG
- Formulated for premature infants
  - 0.2% NaCl
  - No sucrose
  - No preservative

# **Veronate® – Target Indication**

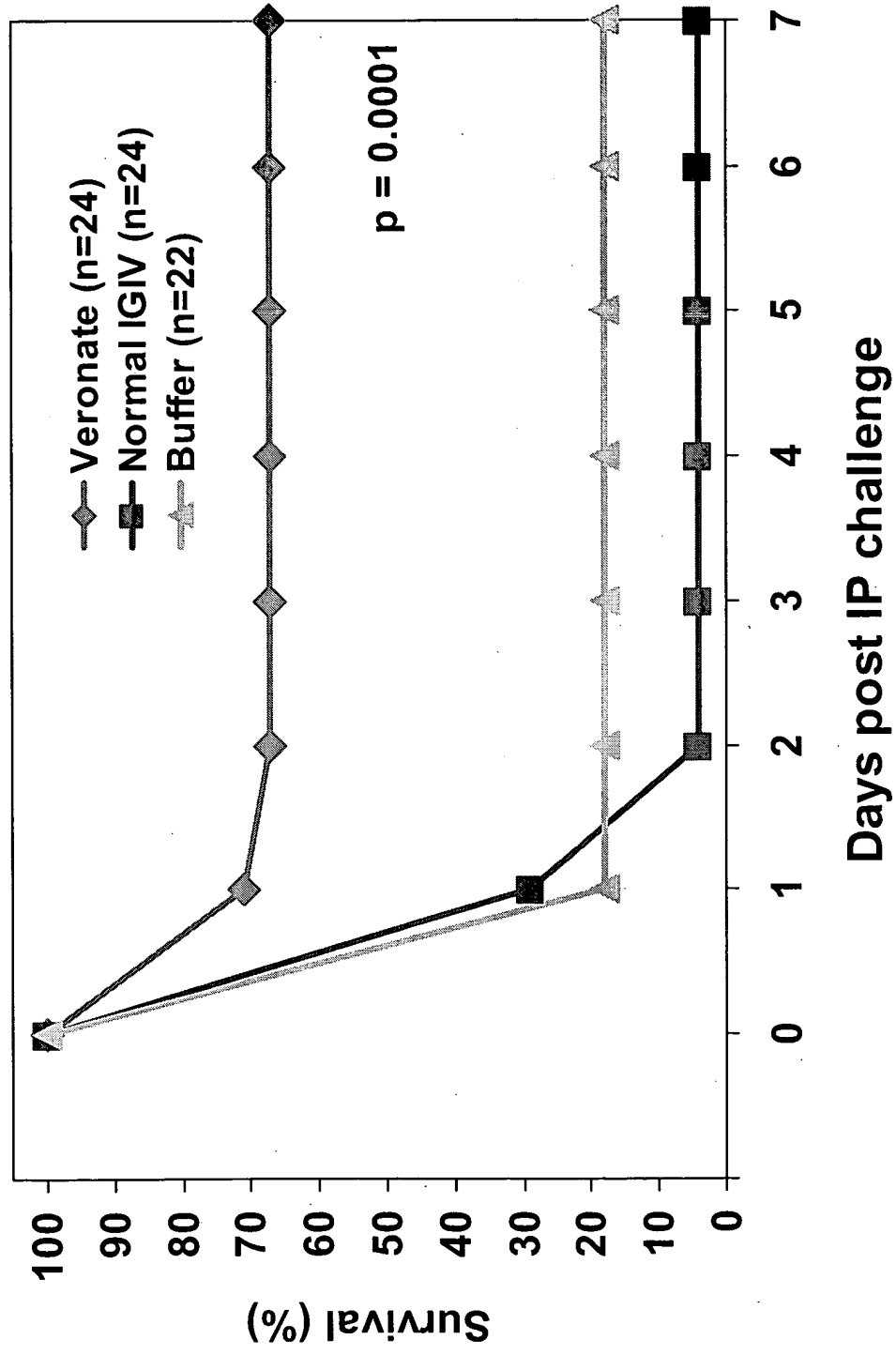
- Premature infants, 500 to 1250 grams
- Prevention of nosocomial infections due to:
  - *S. aureus*
  - *S. epidermidis*
- Other potential benefits
  - Reduction in candidemia
  - Reduce overall mortality



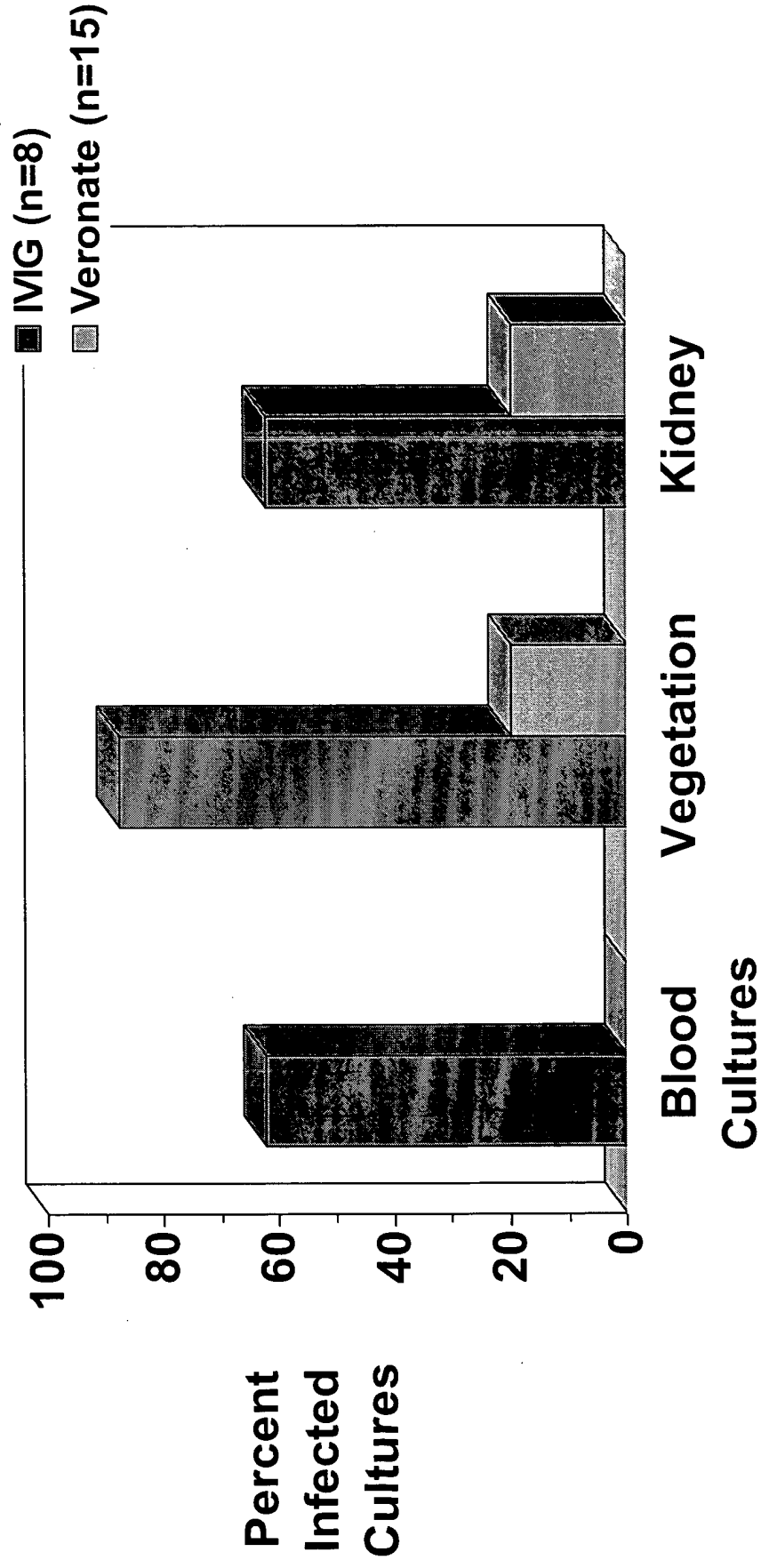
# Pre-Clinical Studies

- Reduced mortality from *S. epidermidis* infection in 3-6 day old rats
- Reduced *S. aureus* and *S. epidermidis* bacteremia and tissue invasion in **prophylaxis** rabbit endocarditis model
- Reduced tissue invasion by both *S. aureus* and *S. epidermidis* in **treatment** of endocarditis in rabbit model

# Veronate Prevents *S. epidermidis* Mediated Mortality in a Suckling Rat Model



# ***Veronate Reduces the Incidence of S. epidermidis Infection in a Rabbit Model of Infectious Endocarditis***



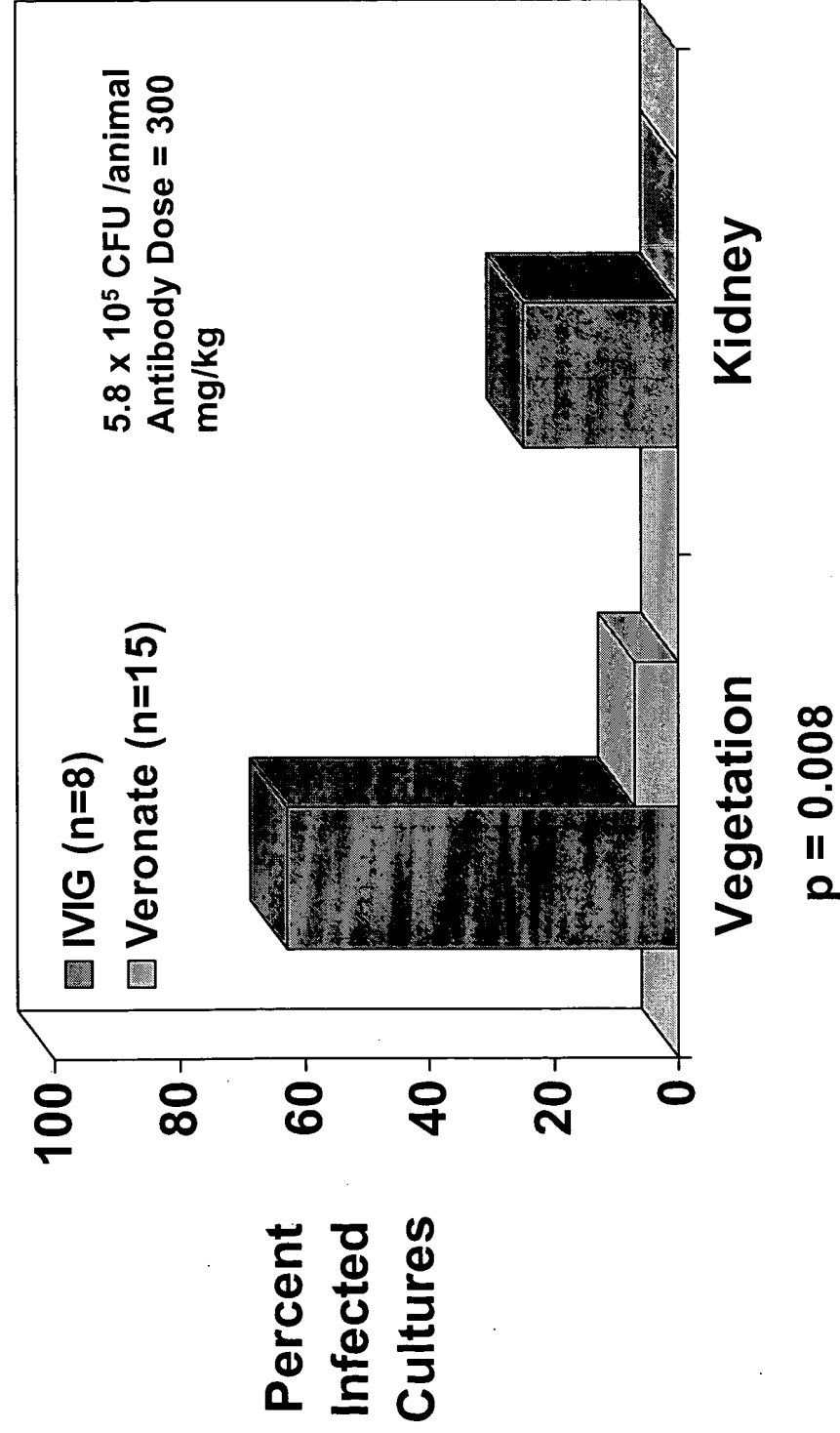
$p < 0.04$

$p < 0.03$

$p < 0.05$



# ***Veronate Reduces the Incidence of *S. aureus* Infection in a Rabbit Model of Infectious Endocarditis***



# Summary of Phase II Results

- Veronate was well tolerated
  - 1,280 doses administered
- No significant difference in AE's or SAE's between placebo and treatment groups
- 750 mg/kg dose selected for pivotal Phase III trial
- Relative reductions between placebo and 750 mg/kg treatment cohorts on an intent-to-treat basis:
  - *S. aureus* infections – 63%
  - Fungal infections – 67%
  - All-cause mortality – 36%



# ***Summary of the Trends in Phase II***

- ▣ Magnitude of the observed differences in infection rates ~60%
- ▣ Differences observed at the highest dose tested
- ▣ Dose-response by time-to-onset analysis
- ▣ Differences for the Veronate targeted organisms
- ▣ Lack of effect on non-targeted organisms
  - ▣ Biologically plausible link to *Candida* spp